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5.75.008

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	December 6, 2013
Subject:	Cyclobenzaprine Powder	**Page:**	1 of 4

Last Review Date: March 8, 2024

Cyclobenzaprine Powder

Description

Cyclobenzaprine Powder

Background
Cyclobenzaprine is a muscle relaxant which relieves muscle spasm of local origin without interfering with muscle function. Cyclobenzaprine acts primarily at the brain stem (and to a lesser extent at spinal cord level) to relieve skeletal muscle spasms (1).

Cyclobenzaprine is commercially available as 5mg, 7.5mg, and 10mg immediate release tablets and 15mg and 30mg extended release capsules (2).

Regulatory Status
FDA-approved indication: Cyclobenzaprine is a muscle relaxant indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions (1-2).

Limitations of Use:
Cyclobenzaprine should be used only for short periods (up to 2 or 3 weeks). Cyclobenzaprine has not been found effective in the treatment of spasticity or cerebral palsy (1-2).

Off-label (non-FDA approved) compounded topical preparations of cyclobenzaprine have not been proven to be safe or effective.

Safety and efficacy in patients younger than 18 years of age have not been established (1).

Related policies
Baclofen powder, Tizanidine powder

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cyclobenzaprine powder may be considered **medically necessary** if the conditions indicated below are met.

Cyclobenzaprine powder may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Muscle spasm associated with acute, painful musculoskeletal condition(s)

AND ALL of the following:

1. The immediate release requested **oral** dose does not exceed 10mg/unit
2. The extended release requested oral dose does not exceed 30mg/unit
3. The requested strength is not commercially available

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Cyclobenzaprine is a muscle relaxant indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. There are no clinically controlled studies confirming that topical application of cyclobenzaprine is safe and effective (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Cyclobenzaprine while maintaining optimal therapeutic outcomes.

References

1. Amrix [package insert]. Vandalia, OH: Adare Pharmaceuticals, Inc.; May 2020.
2. Cyclobenzaprine [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; August 2020.

Policy History

Date	Action
October 2013	New addition to PA
December 2013	Annual review
December 2014	Annual editorial review and reference update
December 2015	Annual review
September 2016	Annual review and reference update Policy number changed from 5.06.12 to 5.75.08
September 2017	Annual editorial review and reference update
September 2018	Annual review
September 2019	Annual review and reference update
September 2020	Annual review
March 2021	Annual review
March 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.75.008
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.